OCT - 6 2009

05 510(k) Summary

owner's name:	**BEGO Implant Systems GmbH& Co KG**
address:	Wilhelm Herbst Strasse 1 28359 Bremen Germany
phone:	+49 412 2028 264
fax numbers:	+49 421 2028 44 264
name of contact person:	Martin Ellerhorst
date the summary was prepared:	2009-09-10
Establishment Registration number:	pending
name of the device:	BEGO Semados® S-Line
trade or proprietary name:	BEGO Semados® S-Line
the classification name:	implant, endosseous, root-form (21 CFR 872.3640 Product Code DZE)

Legally marketed device to which your firm is claiming equivalence

Company:

Friadent GmbH

Device:

XIVE Dental Implant System®

510(k) No.: K032158

Device Description

BEGO Semados® S-Line with TiPure^{Plus} Surface is a dental implant system that can be placed subgingivally in both the upper and lower jaw using a one- or two-stage surgical procedure.

Indications:

The Bego Semados® S-line threaded endosseous dental implants are indicated for restorations in the upper and lower jaw (single tooth replacement, abutments for bridgework, partial or complete edentolism)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. Martin Ellerhorst
Head of Technical Department
BEGO Implant Systems GmbH & Co. KG
Wilhelm-Herbst-Straße 1
28359 Bremen
GERMANY

OCT - 6 2009

Re: K090716
Trade/Device Name: BEGO Semados® S-Line
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: September 10, 2009
Received: September 18, 2009

Dear Mr. Ellerhorst:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Susan Runner, D.D.S., M.A.
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K090716 1081

Indications for Use

510(k) Number (if known): __ K090716_____

Device Name: BEGO Semados® S-Line _____

Indications:

The Bego Semados® S-line threaded endosseous dental implants are indicated for restorations in the upper and lower jaw (single tooth replacement, abutments for bridgework, partial or complete edentolism)

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K090716